Sagimet Biosciences Reports Second Quarter 2025 Financial Results and Provides Corporate Updates

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Denifanstat met all primary and secondary endpoints in Phase 3 clinical trial in moderate to severe acne conducted by license partner Ascletis in China

Initiated first-in-human Phase 1 clinical trial of FASN inhibitor TVB-3567 being developed for acne in the U.S.

Phase 1 clinical trial to evaluate the pharmacokinetics (PK) of a combination of denifanstat and resmetirom expected to initiate in 2H 2025; data readout expected 1H 2026

SAN MATEO, Calif., Aug. 13, 2025 (GLOBE NEWSWIRE) -- Sagimet Biosciences Inc. (Nasdaq: SGMT), a clinical-stage biopharmaceutical company developing novel therapeutics targeting dysfunctional metabolic and fibrotic pathways, today reported financial results for the quarter ended June 30, 2025, and provided recent corporate updates.

"We are making strong progress advancing our differentiated therapeutics, which are in development for the treatment of MASH and acne," said David Happel, Chief Executive Officer of Sagimet. "Following our license partner Ascletis' announcement that denifanstat met all primary and secondary endpoints in its Phase 3 clinical trial in moderate to severe acne in China, in June, we initiated a Phase 1 clinical trial of our second FASN inhibitor, TVB-3567, for development of an acne indication. Additionally, pending consultation with regulatory authorities, we plan to initiate a Phase 1 clinical trial to evaluate the PK and tolerability of a combination of our FASN inhibitor denifanstat and resmetirom in the second half of 2025 as the first step towards development of a combination product for patients living with MASH. We continue to believe in the significant therapeutic potential of FASN inhibition across multiple disease states and are pioneering the development of our FASN inhibitors to benefit underserved patients," he concluded.

Recent Corporate Highlights

- In June, the Company's license partner Ascletis Bioscience Co. Ltd. (Ascletis) reported that denifanstat met all primary and secondary endpoints and was generally well-tolerated in a Phase 3 clinical trial for the treatment of moderate to severe acne vulgaris in China. The randomized, double-blind, placebo-controlled, multicenter clinical trial evaluated the safety and efficacy of denifanstat for the treatment of patients with moderate to severe acne in China with 480 enrolled patients randomized 1:1 to receive denifanstat 50mg or placebo, once daily for 12 weeks. Ascletis reported that:
  - All primary endpoints in the Phase 3 trial were met, including:
    - the percentage of treatment success (defined as an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) with at least a 2-point decrease from baseline) (denifanstat 33.2% vs. placebo 14.6%, p<0.0001),
    - the percentage change in total lesion count (denifanstat -57.4% vs. placebo -35.4%, p<0.0001) and
    - the percentage change in inflammatory lesion count (denifanstat -63.5% vs. placebo -43.2%, p<0.0001).
  - The secondary endpoint of change in non-inflammatory lesion count was also met (denifanstat -51.9% vs. placebo -28.9%, p<0.0001).
  - Denifanstat was generally well-tolerated and, following 12 weeks of once-daily oral administration at 50 mg, the incidence rates of treatment-emergent adverse events (TEAE) were comparable between denifanstat and placebo. No incidence rate of TEAEs in any category exceeded 10%.

These Phase 3 results underline the potential of FASN inhibition as a novel mechanism of action to address acne, a condition that impacts more than 50 million people in the U.S. annually, and which has seen limited innovation over the past 40 years.

- In June 2025, the Company initiated a first-in-human Phase 1 clinical trial of TVB-3567 which is being developed for an acne indication in the U.S. The Phase 1 clinical trial is a randomized double-blind placebo-controlled trial designed to evaluate the safety, tolerability, PK and pharmacodynamics of TVB-3567 in healthy participants with or without acne. The trial is comprised of several parts including single ascending dose cohorts and multiple ascending dose cohorts in participants without acne, followed by testing in participants with acne including evaluation of pharmacodynamic biomarkers.
- The Company held a Key Opinion Leader (KOL) event and webcast on June 16 (link here) featuring Neal Bhatia, MD (Director of Clinical Dermatology at Therapeutics Clinical Research in San Diego). In the webcast, Dr. Bhatia reviewed the results of Ascletis' Phase 3 trial of denifanstat in moderate to severe acne and discussed the study design of our recently

initiated Phase 1 clinical trial of TVB-3567.

- The Company also hosted a KOL event and webcast on May 29 (link here) featuring Rohit Loomba, MD, MHSc (Professor of Medicine, Chief, Division of Gastroenterology and Hepatology, and Director, MASLD Research Center, University of California San Diego), who discussed the potential for developing a combination of denifanstat, a fat synthesis inhibitor, with a fat oxidizer, such as thyroid hormone beta receptor agonist, resmetirom, to treat advanced metabolic dysfunction-associated steatohepatitis (MASH). The planned development program builds upon the successful results of the Phase 2b FASCINATE-2 clinical trial of denifanstat in MASH F2-F3 patients, particularly in more advanced F3 stage patients, as well as on preclinical data demonstrating the synergistic effect of a FASN inhibitor combined with resmetirom on important liver disease markers. The event also provided an overview of the planned Phase 1 PK clinical trial of the denifanstat and resmetirom combination, and a discussion on the potential benefits of combination therapy to treat patients living with advanced MASH.

Publications and Presentations

- In May 2025, Sagimet presented three poster presentations featuring additional analyses from the Phase 2b FASCINATE-2 trial of denifanstat in MASH at the European Association for the Study of Liver (EASL) Congress 2025. The posters focused on antifibrotic effects of denifanstat in difficult-to-treat patients (link here), new bile acid biomarkers to measure denifanstat response (link here) and alternative endpoints to liver biopsy such as MRI to detect patient improvement (link here).

Anticipated Upcoming Milestones

- Sagimet plans to initiate a Phase 1 clinical trial to evaluate the PK and tolerability of a combination of denifanstat and resmetirom in the second half of 2025, with an anticipated data readout in the first half of 2026.
- Sagimet initiated a Phase 1 clinical trial of TVB-3567, for development of an acne indication. Contingent on discussions with regulatory authorities and the outcome of the Phase 1 trial, the Company anticipates starting the Phase 2 program in moderate to severe acne patients in 2026.

Financial Results for the Three and Six Months Ended June 30, 2025

- **Cash, cash equivalents and marketable securities** as of June 30, 2025 were $135.5 million.
- **Research and development expense** for the three and six months ended June 30, 2025, was $7.2 million and $22.6 million, respectively, compared to $6.3 million and $11.6 million for the three and six months ended June 30, 2024, respectively.
- **General and administrative expense** for the three and six months ended June 30, 2025 was $4.7 million and $9.2 million, respectively, compared to $4.3 million and $7.8 million for the three and six months ended June 30, 2024, respectively.
- **Net loss** for the three and six months ended June 30, 2025 was $10.4 million and $28.6 million, respectively, compared to $8.1 million and $14.7 million for the three and six months ended June 30, 2024, respectively.

About Sagimet Biosciences

Sagimet is a clinical-stage biopharmaceutical company developing novel fatty acid synthase (FASN) inhibitors that are designed to target dysfunctional metabolic and fibrotic pathways in diseases resulting from the overproduction of the fatty acid, palmitate. Sagimet's lead drug candidate, denifanstat, is an oral, once-daily pill and selective FASN inhibitor in development for the treatment of metabolic dysfunction associated steatohepatitis (MASH). FASCINATE-2, a Phase 2b clinical trial of denifanstat in MASH with liver biopsy-based primary endpoints, was successfully completed with positive results. Denifanstat has been granted Breakthrough Therapy designation by the FDA for the treatment of non-cirrhotic MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), and end-of-Phase 2 interactions with the FDA have been successfully completed, supporting the advancement of denifanstat into further development. Sagimet has recently initiated a Phase 1 first-in-human clinical trial with a second oral FASN inhibitor drug candidate, TVB-3567, that is planned to be developed for acne in the U.S. For additional information about Sagimet, please visit www.sagimet.com.

About MASH

Metabolic-dysfunction associated steatohepatitis (MASH) is a progressive and severe liver disease which is estimated to impact more than 115 million people worldwide, for which there is only one recently approved treatment in the United States and no currently approved treatments in Europe. In 2023, global liver disease medical societies and patient groups formalized the decision to rename non-alcoholic fatty liver disease (NAFLD) to metabolic dysfunction-associated steatotic liver disease (MASLD) and nonalcoholic steatohepatitis (NASH) to MASH. Additionally, an overarching

term, steatotic liver disease (SLD), was established to capture multiple types of liver diseases associated with fat buildup in the liver. The goal of the name change was to establish an affirmative, non-stigmatizing name and diagnosis.

About Acne

There are 5.1 million acne patients treated by dermatologists annually in the U.S., and a total U.S. acne market of over 50 million people.[1,2] There is no cure for acne; and due to its pathology, most patients require chronic management and multiple courses of treatment for flare control annually. Additionally, adherence to topical therapies is lower than with oral agents, with an estimated 30% to 40% of patients not adhering to their topical treatments.[3]

1. Bickers DR, et al. *J Am Acad Dermatol*. 2006;55(3):490-500.
2. American Academy of Dermatology. Burden of Skin Disease. 2017. www.aad.org/BSD.
3. Purvis CG, Balogh EA, Feldman SR. Clascoterone: How the Novel Androgen Receptor Inhibitor Fits Into the Acne Treatment Paradigm. Ann Pharmacother. 2021;55(10):1297-1299. doi:10.1177/1060028021992055.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of, and made pursuant to the safe harbor provisions of, The Private Securities Litigation Reform Act of 1995. All statements contained in this press release, other than statements of historical facts or statements that relate to present facts or current conditions, including but not limited to, statements regarding: the expected timing of the presentation of data from ongoing clinical trials, Sagimet's clinical development plans and related anticipated development milestones, Sagimet's cash and financial resources and expected cash runway. These statements involve known and unknown risks, uncertainties and other important factors that may cause Sagimet's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, these statements can be identified by terms such as "may," "might," "will," "should," "expect," "plan," "aim," "seek," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "forecast," "potential" or "continue" or the negative of these terms or other similar expressions.

The forward-looking statements in this press release are only predictions. Sagimet has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that Sagimet believes may affect its business, financial condition and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond Sagimet's control, including, among others: the clinical development and therapeutic potential of denifanstat, TVB-3567 or any other drug candidates Sagimet may develop; Sagimet's ability to advance drug candidates into and successfully complete clinical trials within anticipated timelines; Sagimet's relationship with Ascletis, and the success of its development efforts for denifanstat; the accuracy of Sagimet's estimates regarding its capital requirements; and Sagimet's ability to maintain and successfully enforce adequate intellectual property protection. These and other risks and uncertainties are described more fully in the "Risk Factors" section of Sagimet's most recent filings with the Securities and Exchange Commission and available at www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in these forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, Sagimet operates in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that Sagimet may face. Except as required by applicable law, Sagimet does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Investor Contact:
Joyce Allaire
LifeSci Advisors
JAllaire@LifeSciAdvisors.com

Media Contact:
Michael Fitzhugh
LifeSci Advisors
mfitzhugh@lifescicomms.com

SAGIMET BIOSCIENCES INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(in thousands, except for share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 7,248	$ 6,313	$ 22,590	$ 11,575
General and administrative	4,677	4,276	9,200	7,782
Total operating expenses	11,925	10,589	31,790	19,357
Loss from operations	(11,925)	(10,589)	(31,790)	(19,357)

Total other income	1,539	2,471	3,228	4,610
Net loss	$ (10,386)	$ (8,118)	$ (28,562)	$ (14,747)
Net loss per share, basic and diluted	$ (0.32)	$ (0.25)	$ (0.89)	$ (0.48)
Weighted-average shares outstanding, basic and diluted	32,195,366	31,913,887	32,195,355	30,476,657
Net loss	$ (10,386)	$ (8,118)	$ (28,562)	$ (14,747)
Other comprehensive loss:				
Net unrealized loss on marketable securities	(45)	(30)	(154)	(53)
Total comprehensive loss	$ (10,431)	$ (8,148)	$ (28,716)	$ (14,800)

SAGIMET BIOSCIENCES INC.

CONDENSED BALANCE SHEETS

(unaudited)

(in thousands)

	As of	
	June 30, 2025	**December 31, 2024**
Cash, cash equivalents and marketable securities	$ 135,466	$ 158,658
Total assets	$ 137,407	$ 160,259
Current liabilities	$ 7,247	$ 4,454
Stockholders' equity	$ 130,160	$ 155,805
Liabilities and stockholders' equity	$ 137,407	$ 160,259

Source: Sagimet Biosciences Inc.